Izervay™ (avacincaptad pegol) – New drug approval

- On August 5, 2023, Astellas and IVERIC bio announced the FDA approval of Izervay (avacincaptad pegol), for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

- GA is a severe form of AMD affecting an estimated 1.5 million people in the U.S. Without treatment, an estimated 66% of people with GA may become blind or severely visually impaired.

- Izervay is a complement C5 inhibitor, and the second drug FDA approved for GA. Apellis' Syfovre™ (pegcetacoplan), a compliment C3 inhibitor, was approved in February 2023 for GA.

- The efficacy of Izervay was established in two randomized, double-masked, sham-controlled, 18- and 12-month studies (GATHER1 and GATHER2, respectively) in patients with GA due to AMD. In total, 292 patients were treated with avacincaptad pegol 2 mg, and 332 patients received sham. In both studies, the primary endpoint was the mean rate of GA growth (slope) from baseline to month 12.

    — In each study, there was a statistically significant reduction of the rate of GA growth (0.10 mm/year; $p < 0.01$ in GATHER1 and 0.05 mm/year; $p < 0.01$ in GATHER2 with square root transformed data) in patients treated with Izervay compared to sham.

	GATHER1		GATHER2	
	Izervay	**Sham**	**Izervay**	**Sham**
GA rate of growth (mm^2/year)	1.22	1.89	1.75	2.12
Difference (95% CI) (mm^2/year)	0.67 (0.21, 1.13) $p < 0.01$		0.38 (0.12, 0.63) $p < 0.01$	

- Izervay is contraindicated in patients with:

    — Ocular or periocular infections
    — Active intraocular inflammation

- Warnings and precautions for Izervay include endophthalmitis and retinal detachment; neovascular AMD; increase in intraocular pressure (IOP).

- The most common adverse reactions with Izervay use were hemorrhage, increased IOP, blurred vision, and neovascular AMD.

- The recommended dose for Izervay is 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately every 28 ± 7 days) for up to 12 months.

    — Izervay must be administered by a qualified physician.

- Astellas plans to launch Izervay in 2 to 4 weeks. Izervay will be available as a 20 mg/mL solution in a single-dose vial